IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: March 9, 2007)

DO NOT PUBLISH

JERRIL FANT and DAWN FANT, as father and mother of their daughter, LYNZE FANT,	)	
Petitioners,	)	
v.	)	No. 02-1419V
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	Prevnar Vaccine; Transverse Myelitis; Entitlement; Proffer on Damages
Respondent.	)	

DECISION ON ENTITLEMENT AND DAMAGES[1]

Petitioners, Jerril Fant and Dawn Fant (Mr. Fant and Ms. Fant or the Fants), as father and mother of their daughter, Lynze Fant (Lynze), seek compensation under the National Vaccine Injury Compensation Program (Program).[2] On July 5, 2000, Lynze suffered the acute onset of transverse myelitis. *See generally* Petitioners' exhibits (Pet. ex.) at 16-167. Transverse myelitis is an "inflammation of the spinal cord" that "spans the width of the entire cord at a given level." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1209 (30th ed. 2003). The Fants relate Lynze's transverse myelitis to a pneumococcal conjugate (Prevnar) vaccination that Lynze received on June 27, 2000. *See* Petition (Pet.) ¶ VII. According to the Fants, Lynze is not able to walk now "without

[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

the assistance of braces or a walker." *Id.* In addition, the Fants assert that Lynze "has difficulty speaking." *Id.* The Fants pursue necessarily their claim upon an actual causation theory. *See, e.g.* Memorandum in Support of Petitioner's Petition for Vaccine Compensation and Her Expert's Opinion (P. Memo.).

THE LEGAL FRAMEWORK

The United States Court of Appeals for the Federal Circuit (Federal Circuit) endorses the Restatement (Second) of Torts as a "uniform approach" to resolving actual causation issues in Program cases. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). Thus, to prevail, a petitioner must demonstrate by the preponderance of the evidence that (1) "but for" the administration of a vaccine listed on the Vaccine Injury Table (Table), petitioner would not have been injured, and (2) a vaccine listed on the Table was "a 'substantial factor' in bringing about" petitioner's injury. *Id.* at 1352, citing Restatement (Second) of Torts § 431. The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See In re Winship,* 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. JAMES, CIVIL PROCEDURE 250-51 (1965)). Mere conjecture or speculation will not meet the preponderance of evidence standard. *See Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612, 624 (1995), *aff'd*, 73 F.3d 381 (1995).

The simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148-50 (Fed. Cir. 1992). Rather, long-standing, well-established Federal Circuit precedent instructs that a petitioner establishes a *prima facie* actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Capizzano v. Secretary of HHS*, 440 F.3d 1317 (Fed. Cir. 2006); *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994), citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d at 1148. The "*prima facie* case" is "a party's production of enough evidence to allow the fact-finder to infer the fact at issue and rule in the party's favor." BLACK'S LAW DICTIONARY 1228 (8th ed. 2004).

The centerpiece of a *prima facie* actual causation case is the "medical theory." In a petitioner's *prima facie* actual causation case, the "medical theory" is the "reliable medical or scientific explanation" buttressing the proposition that a vaccine listed on the Table can cause a particular injury. *Grant*, 956 F.2d at 1148. Thus, the medical theory must consist of "more than subjective belief." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993); *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (An "expert's bald assurance of validity is not enough."). Instead, the medical theory must be grounded "in the methods and procedures of" medicine or science. *Daubert*, 509 U.S. at 590; *see also*

Daubert, 43 F.3d at 1317 ("[T]he analysis undergirding" the medical theory must fall "within the range of accepted standards governing" medical or scientific research.). Nevertheless, the medical theory need not be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. The medical theory need only be "logical" and "probable," given "the circumstances of the particular case." *Id.* at 548-49.

If a petitioner mounts a *prima facie* actual causation case, respondent may present rebuttal evidence. In respondent's rebuttal case, respondent may dispute perhaps a petitioner's medical theory through medical expert testimony. Or, respondent may challenge perhaps the factual assumptions that a petitioner's expert adopts in rendering an opinion. Then, the special master weighs all of the evidence to determine if a petitioner has met the evidentiary burden on the merits of the actual causation case.

However, a petitioner does not gain Program compensation upon proving successfully the merits of the petitioner's actual causation case. *See Grant*, 956 F.2d at 1149. The Vaccine Act requires specifically the special master to "also determine that 'there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine,'" or "alternative etiologies." *Grant*, 956 F.2d at 1149, citing § 300aa-13(a)(1). The Vaccine Act provides that "factors unrelated to the administration of the vaccine," or alternative etiologies

> may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

§ 300aa-13(a)(2)(B). The Vaccine Act provides also that "factors unrelated to the administration of the vaccine," or alternative etiologies, do not encompass "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." § 300aa-13(a)(2)(A).

The Federal Circuit has decreed that the burden of proving alternative actual causation rests squarely with respondent. *See, e.g.*, *Althen*, 418 F.3d at 1281-82; *Knudsen*, 35 F.3d at 547, citing *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 376 (Fed. Cir. 1994). In addition, the Federal Circuit has decreed that "the standards that apply to a petitioner's proof of actual causation in fact" are "the same as those that apply to the government's proof of alternative actual causation in fact." *Knudsen*, 35 F.3d at 549. Thus, respondent establishes a *prima facie* alternative actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the [factor unrelated to the administration of the vaccine] and the injury; (2) a logical sequence of cause and effect showing that the [factor unrelated to the administration of the vaccine] was the reason for the injury; and (3) a showing of a proximate temporal relationship between [the factor unrelated to the administration of the vaccine] and injury." *Althen*, 418 F.3d at 1278; *see also Capizzano v. Secretary of HHS*, 440 F.3d 1317 (Fed. Cir. 2006); *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994), citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d at 1148.

If respondent mounts a *prima facie* alternative actual causation case, a petitioner may present rebuttal evidence. Then, the special master weighs all of the evidence to determine if respondent has met the evidentiary burden on the merits of the alternative actual causation case. However, American tort jurisprudence recognizes that many cases involve "a number of events" which have "an appreciable effect" on a party's "harm." Restatement 2d Torts § 433 cmt. d; *see also Shyface*, 165 F.3d at 1352. Thus, in addressing respondent's alternative actual causation case, a petitioner need not eliminate *per se* other causes for the petitioner's injury. *See, e.g.*, *Shyface*, 165 F.3d 1344; *but see Althen*, 418 F.3d at 1281 (A prong of a proposed actual causation formula "requiring that the claimant provide proof of . . . the elimination of other causes is merely a recitation of this court's well-established precedent" regarding actual causation.). Rather, in addressing respondent's alternative actual causation case, a petitioner need only establish that the administration of a vaccine constitutes a substantial factor in the development of an injury, even in the presence of other potential causes. *See Shyface*, 165 F.3d at 1352, citing Restatement 2d Torts, § 430 cmt. d ("It is not necessary that [the administration of a vaccine] be *the* cause, using the word "the" as meaning the sole and even the predominant cause.") (emphasis in original). In contrast, by mandating the showing that an alternative "agent" is "*principally* responsible for causing the petitioner's illness, disability, injury, condition, or death," § 300aa-13(2)(B) (emphasis added), Congress expected apparently any factor unrelated to the administration of a vaccine to be the "predominant" cause of a petitioner's injury, thus preventing the administration of a vaccine "from being a substantial factor" in the petitioner's injury. Restatement 2d Torts § 433, cmt. d; *see also Knudsen*, 35 F.3d at 549-50.

BACKGROUND

The parties do not dispute the relevant facts.[3] Lynze was delivered by cesarean section on November 16, 1999. *See* Pet. ex. at 280. As an infant, Lynze received routine pediatric medical care from Kenneth R. Robertson, M.D. (Dr. Robertson), at Memphis Children's Clinic, in Bartlett, Tennessee. *See* Pet. ex. at 4-13. Except for minor maladies–such as a bloody stool attributed to a hemorrhoid and a rectal tear in December 1999, *see* Pet. ex. at 4; "reflux," Pet. ex. at 5, 12; and

[3] At an evidentiary hearing in Memphis, Tennessee, Mr. Fant, Ms. Fant and Josie Fant (Mrs. Fant), Lynze's paternal grandmother, testified extensively regarding Lynze's symptoms preceding the onset of Lynze's transverse myelitis. *See generally* Transcript (Tr. I), filed September 3, 2003. In the special master's view, the value of the fact testimony is dubious. Congress prohibited special masters from awarding compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a). Numerous cases construe § 300aa-13(a). The cases reason that "special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone." *Raley v. Secretary of HHS*, No. 91-0732V, 1998 WL 681467, *9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998). At an evidentiary hearing in Washington, D.C., the Fants' medical expert, Raul N. Mandler, M.D. (Dr. Mandler), did not attribute medical significance to some of the symptoms that Mr. Fant, Ms. Fant and Mrs. Fant described. *See, e.g.*, Transcript (Tr. II), filed September 12, 2003, at 99-102. Regardless, the lay testimony is not critical ultimately to the special master's analysis of the case.

several episodes of congestion, *see* Pet. ex. at 5, 10–Lynze grew and developed well between birth and July 2000. *See generally* Pet. ex. at 4-13, 17G, 17J, 20-21. Dr. Robertson, or a member of his staff, administered an array of childhood vaccines to Lynze, including diphtheria-tetanus-acellular pertussis (DTaP), inactivated polio vaccine (IPV) and Comvax[4] on January 18, 2000, *see* Pet. ex. at 8; DTaP, IPV and Comvax on March 13, 2000, *see* Pet. ex. 10; and DTaP, IPV and Prevnar on May 23, 2000. *See* Pet. ex. at 12. Lynze's medical records that are directly contemporaneous with Lynze's January 18, 2000 vaccinations, Lynze's March 13, 2000 vaccinations and Lynze's May 23, 2000 vaccinations do not reflect that Lynze experienced any adverse reactions to any of the vaccinations.[5] Dr. Robertson, or a member of his staff, administered a second Prevnar to Lynze on June 27, 2000. *See* Pet. ex. at 2; *see also* Pet. ex. at 12.

As Mr. Fant "placed" Lynze "in a sitting position" at approximately 4:30 p.m., on July 5, 2000, he "felt a pop in" Lynze's "back." Pet. ex. at 17G. Lynze "went limp." *Id.* Mr. Fant noticed that Lynze "wouldn't move her legs." Pet. ex. at 17A.

Mr. Fant transported Lynze to the LeBonheur Children's Medical Center Urgent Care Clinic in Cordova, Tennessee. *See* Pet. ex. at 17E. The facility referred Mr. Fant to the LeBonheur Children's Medical Center Emergency Department in Memphis, Tennessee. *See* Pet. ex. at 17A, 17E. In the Emergency Department, Lynze was "crying." Pet. ex. at 17A. A nurse observed that Lynze showed "some" movement in her "legs." *Id.* An Emergency Department physician suspected a "spinal cord injury." *Id.* The Emergency Department physician ordered a radiographic series of Lynze's spine. *See* Pet. ex. at 118. In addition, the Emergency Department physician planned consultations with an orthopedist and a neurosurgeon. *See* Pet. ex. at 17A.

A staff physician evaluated Lynze at approximately 11:45 p.m., on July 5, 2000. *See* Pet. ex. at 17G. Although Lynze was sleeping, she aroused "easily." Pet. ex. at 17G. According to the staff physician, Lynze tracked "well." *Id.* However, according to the staff physician, Lynze displayed "[decreased] tone in [her] L[eft]U[pper]E[xtremity] compared to [her] right U[pper]E[xtremity]." *Id.* And, according to the staff physician, Lynze was "not moving" her lower extremities "spontaneously." *Id.* The staff physician noted that an initial "x-ray" showed "no bony abnormality" in Lynze's spine. *Id.* The staff physician determined to "repeat" the radiographic series. *Id.*; *see*

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[4] Haemophilus b conjugate vaccine and Hepatitis B vaccine.

[5] However, on July 18, 2000, Dr. Robertson completed a Vaccine Adverse Events Reporting System (VAERS) form. *See* Pet. ex. at 412. Dr. Robertson stated that Lynze exhibited "[questionable] early stiffening" that occurred "1-2 w[ee]ks before" the diagnosis of transverse myelitis on July 5, 2000, placing possibly the onset of the "stiffening" between four weeks and six weeks after Lynze's May 23, 2000 Prevnar vaccination. Pet. ex. at 412. Dr. Robertson described the behavior as "periodic." *Id.* According to Dr. Robertson, the behavior was "not consistent" in the "lower extremities." *Id.* In addition, a VAERS form dated August 7, 2000, indicates that Lynze suffered "a rash" at some point following her May 23, 2000 Prevnar vaccination. Pet. ex. at 414; *see also* Pet. ex. at 410.

also Pet. ex. at 119 (physician's order for "M[agnetic]R[esonance]I[maging] spine cervical"). At approximately 11:55 p.m., on July 5, 2000, the staff physician transferred Lynze from the Emergency Department to the LeBonheur Children's Medical Center Neurosurgery Department for "observation." Pet. ex. at 119.

Lynze underwent an MRI on July 6, 2000. *See* Pet. ex. at 44, 166. Lynze's "cervical and thoracic cord appear[ed] widened with decreased signal within it on T1-weighted images and increased signal in this region on T2-weighted images." Pet. ex. at 166. The radiologist who interpreted the MRI concluded that the MRI revealed "[e]dema in the cervicothoracic spinal cord with normal lumbar spinal cord." *Id.* The radiologist who interpreted the MRI suspected "myelitis." *Id.*

Lynze underwent also a lumbar puncture (LP) on July 6, 2000, "to r[ule]/o[ut] [an] infectious etiology" for her sudden "episode of weakness." Pet. ex. at 138-39; *see also* Pet. ex. at 120. The LP revealed "increased protein of 64, blood glucose 55, and 6 white blood cells." Pet. ex. at 17J; *see also* Pet. ex. at 39. A "C[erebro]S[pinal]F[luid] Immunology Profile" was normal, showing "no evidence of oligoclonal banding." Pet. ex. at 33.

A neurologist evaluated Lynze on July 6, 2000. *See* Pet. ex. at 20.[6] After examining Lynze, and after reviewing Lynze's MRI, the neurologist concluded that Lynze had sustained "transverse myelitis." Pet. ex. at 20. The neurologist placed the "site of myelitis" in Lynze's "lower spinal cord[,] mainly affecting C[ervical Nerve]$_7$-T[horacic Nerve]$_1$ level." Pet. ex. at 144. The neurologist recommended a five-day course of "Solumedrol," followed by an 11-day course of "prednisone." Pet. ex. at 20.

By 8:00 p.m., on July 7, 2000, Lynze showed a measure of "improved tone" in her extremities. Pet. ex. at 141. In subsequent days, Lynze continued to experience "clinical improvement." Pet. ex. at 145. However, Lynze developed a "persistent fever." Pet. ex. at 148. A battery of tests, including "blood cultures, urine cultures and a chest x-ray," returned "negative" results. Pet. ex. at 17J; *see also* Pet. ex. at 17K, 162 ("[R]ectal swab and nasopharyngeal swab for viral cultures" were "negative").

A physical therapist assessed Lynze on July 10, 2000. *See* Pet. ex. at 17N-17O. The physical therapist noted significant deficits in Lynze's mobility. *See id.* The physical therapist "educated" Mr. Fant "about positioning" and exercises to promote range of motion in Lynze's extremities. Pet. ex. at 17O. In addition, the physical therapist recommended formal physical therapy at least twice each week. *See id.*

Lynze exhibited "marginal clinical improvement" following the transition from "I[ntra]V[enous] steroids" to oral "steroids." Pet. ex. at 17J. On July 12, 2000, the neurologist

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[6] The neurologist may have been Masanori Igarashi, M.D. (Dr. Igarashi). *See* Pet. ex. at 17K (signature line for Masanori Igarashi, M.D.); Pet. ex. at 20 (signature line for "consultant").

"elected to give" Lynze a two-day course of "high dose I[ntra]V[enous]I[mmuno]G[lobulin]." Pet. ex. at 157. The neurologist reasoned that "high dose IVIG" had "been reported to be beneficial for the patient who did not respond [to] steroid [treatment] very well." *Id.*

Lynze "tolerated" IVIG treatment "without problems." Pet. ex. at 17J; *see also* Pet. ex. at 159, 162. She demonstrated "improved movement in all extremities." *Id.* Nevertheless, she did not return to "baseline." Pet. ex. at 17K; *see also* Pet. ex. at 162.

On July 14, 2000, the neurologist determined to discharge Lynze from the hospital with instructions "to complete" the course of "oral prednisone." Pet. ex. at 161. The neurologist advised the Fants to arrange "outpatient P[hysical]T[herapy]." *Id.* In addition, the neurologist advised the Fants to "follow-up with" several of Lynze's physicians. Pet. ex. at 17K; *see also* Pet. ex. at 161. Despite a "continued low-grade fever," Lynze appeared "clinically well" and "stable" upon discharge. Pet. ex. at 17K.

On July 19, 2000, Lynze presented to Germantown Hospital in Germantown, Tennessee, for an occupational therapy pediatric evaluation and a pediatric developmental physical therapy evaluation. *See* Pet. ex. at 168, 172; Pet. ex. at 169-70. The occupational therapist determined that Lynze was "developmentally functioning at the 1.5 month level" in "both" fine motor and gross motor activities. Pet. ex. at 172. The occupational therapist recommended "6-9 months" of "occupational therapy" to address Lynze's "U[pper]E[xtremity]/hand use and developmental skills." *Id.* The physical therapist determined that Lynze's fine motor skills and gross motor skills ranged between the "one-month level" and the "two-month level." Pet. ex. at 169. The physical therapist recommended "3 m[on]ths" of physical therapy concentrating on "neuro-facilitation to promote motor patterns for upright positions and locomotion." Pet. ex. at 170.

By December 17, 2001, Lynze was "making good progress" in her occupational and physical therapy programs. Pet. ex. at 283. She experienced "no difficulty using the hands." *Id.* In addition, she was "walking well with a two-wheeled walker." *Id.* However, Lynze was "not doing well" with language development. *Id.* While Lynze seemed "to understand" well, she "only" knew "about 3 words." *Id.*[7]

Lynze continued to participate in various therapy programs through a number of providers. *See, e.g.* Pet. ex. at 179-80, 183-247, 332-33, 410A-12A. Lynze encountered significant difficulty with independent ambulation. *See, e.g.*, Pet. ex. at 180, 411A; *see also* Notice of Filing of Fourth Set of Supplemental Documents, filed February 21, 2006, Exhibit 9, U.T. Medical Group at 1 (Lynze required "heel cord lengthening procedure"). In addition, Lynze encountered significant difficulty

[7] It appears that Lynze underwent an "initial speech-language evaluation" on August 20, 2001, that "revealed a moderate to severe speech/language delay," particularly "decreased receptive and expressive language skills." Pet. ex. at 181. It appears also that Lynze commenced "speech therapy." *Id.*; *see also* Pet. ex. at 283.

with establishing "urinary control." Pet. ex. at 408A; *see also* Notice of Filing of Fourth Set of Supplemental Documents, filed February 21, 2006, Exhibit 6, Pediatric Urology.

THE MEDICAL TESTIMONY

Dr. Mandler

Dr. Mandler received his medical degree from the University of Buenos Aires in Buenos Aires, Argentina. *See* Tr. II at 27. He is certified in neurology by the American Board of Psychiatry and Neurology; in clinical neurophysiology by the American Board of Psychiatry and Neurology; and in electromyography by the American Board of Electrodiagnostic Medicine. *See* Tr. II at 36. He is a Professor of Neurology at The George Washington University Medical Center in Washington, D.C. *See* Tr. II at 34. As a Professor, he teaches medical students and residents. *See* Tr. II at 35. In addition, he maintains a clinical practice. *See* Tr. II at 34. Further, he conducts research. *See* Tr. II at 35. He identified multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS) as his primary research interests. *See* Tr. II at 35.

Dr. Mandler claims extensive experience with transverse myelitis. *See, e.g.*, Tr. II at 35-36. He said that "in the early '90s," he "wrote papers" about Devic's neuromyelitis optica, a condition marked by "transverse myelitis in combination with optic neuritis with normal structures of the brain, brain stem and cerebellum." Tr. II at 35. Now, Dr. Mandler asserted, he consults on "many, many" cases of transverse myelitis each year. Tr. II at 58-59; *see also* Tr. II at 33-34. He is active in the Transverse Myelitis Association. *See* Tr. II at 38. In fact, Dr. Mandler participated in a "symposium" organized by respondent's medical expert, collaborating on "a document" regarding "updated diagnostic criteria" for transverse myelitis. Tr. II at 39.

Dr. Mandler described transverse myelitis as a "central nervous system inflammatory" condition. Tr. II at 44; *see also* Tr. II at 30, 54, 57, 86, 91-92. He said that the incidence of transverse myelitis is "uncommon." Tr. II at 66. According to Dr. Mandler, transverse myelitis is "a syndrome," rather than "a single disease." Tr. II at 36; *see also* Tr. II at 70. Dr. Mandler elaborated that "many factors" or "various mechanisms" may be responsible for transverse myelitis. Tr. II at 36. Indeed, he commented that because the "pathogenesis" of transverse myelitis "is very complex," Tr. II at 61, the medical community does not understand "exactly all the mechanisms that might produce" the condition. Tr. II at 44. Nevertheless, he asserted that transverse myelitis is an "autoimmune" disorder. *Id.*; *see also* Tr. II at 102. He explained that some process "stimulates the immune system" inappropriately, causing "the body" to "confuse" an antigen like "a virus or a bacteria" or a vaccine with the body's "own proteins." Tr. II at 44-46; *see also* Tr. II at 50-51, 57-58, 114. He advanced three potential mechanisms for transverse myelitis: molecular mimicry, microbial superantigen-mediated inflammation and humoral derangement. *See* Tr. II at 95; *see also* Tr. II at 46-50, 56.

Dr. Mandler labeled Prevnar as "the most likely cause of" Lynze's transverse myelitis. Tr. II at 42-43; *see also* Tr. II at 58. He offered several bases for his opinion, including his "knowledge of vaccines;" his understanding that vaccines "can produce transverse myelitis;" the theoretical "mechanisms" of causation and the lack of "any other reason" for Lynze's transverse myelitis. Tr. II at 58; *see also* Tr. II at 63, 114-15. Dr. Mandler posited that Lynze's transverse myelitis represents an "allergic reaction" to Prevnar. Tr. II at 47; *see also* Tr. II at 60, 96. Dr. Mandler maintained that a second exposure or a third exposure to an antigen generates "a mega" immune "response." Tr. II at 63; *see also* Tr. II at 61. He said that most "responses are protective." Tr. II at 63. However, he said, "in some cases, the responses are destructive." Tr. II at 64. In Dr. Mandler's view, Lynze's May 23, 2000 Prevnar vaccination sensitized Lynze to develop an aberrant "booster" effect to Lynze's June 27, 2000 Prevnar vaccination, leading to transverse myelitis. Tr. II at 46-48; *see also* Tr. II at 63-64, 96, 114-15. Dr. Mandler stated that "a first reaction" following an initial exposure to an antigen may not be apparent, Tr. II at 61; *see also* Tr. II at 64, or may "be very minimal." Tr. II at 64; *see also* Tr. II at 61. Thus, he insisted that even in the complete absence of any symptoms after Lynze's May 23, 2000 Prevnar vaccination, he would attribute Lynze's transverse myelitis to Lynze's June 27, 2000 Prevnar vaccination if he were not able to "find any other cause." Tr. II at 63; *see also* Tr. II at 60-61.

Dr. Mandler testified that "the blunt of" Lynze's transverse myelitis "occurred in the spinal cord." Tr. II at 86; *see also* Tr. II at 82, 89, 91. Thus, he acknowledged that Lynze's speech delay is "not related to" Lynze's injury "at the level of the spinal cord" or "the level of the cervical cord." Tr. II at 92. Nevertheless, he insisted that one "cannot rule out" the proposition that Lynze suffered "a generalized disorder of the central nervous system." Tr. II at 89; *see also* Tr. II at 82, 86, 91. Thus, he asserted that Lynze's speech delay is "part of the same process" that led to Lynze's transverse myelitis. Tr. II at 86; *see also* Tr. II at 81-82, 84, 89, 92. As a consequence, Dr. Mandler said that he would consider Lynze's condition to be "transverse myelitis plus," Tr. II at 82, or "a C[entral]N[ervous]S[ystem] neuroinflammatory disorder with predominant affection of the spinal cord but the possibility of an encephalopathy, too." Tr. II at 91.

Douglas A. Kerr, M.D., Ph.D. (Dr. Kerr)

Dr. Kerr received his medical degree from Jefferson Medical College of Thomas Jefferson University in Philadelphia, Pennsylvania. *See* Respondent's exhibit (R. ex.) B at 1. In addition, Dr. Kerr received a Ph.D. in biochemistry and molecular biology from the College of Graduate Studies of Thomas Jefferson University. *See id.* He is certified by the American Board of Psychiatry and Neurology. *See id.* He is an Assistant Professor of Neurology at The Johns Hopkins Hospital in Baltimore, Maryland. *See id.*

In 1999, Dr. Kerr established the Johns Hopkins Transverse Myelopathy Center, "a multi-discipline" department designed "to study transverse myelitis" and to serve as a world-wide "referral source for patients with transverse myelitis." Tr. II at 118-19. He is the Center's Director. *See* R. ex. B at 1; *see also* Tr. II at 118. At the Center, he evaluates "patients who are at varying stages of

recovery from the inflammatory phase of transverse myelitis," recommending "treatments when appropriate." Tr. II at 119; *see also* Tr. II at 126, 184-85. In addition, he consults by telephone "two to three times a day" on other cases of transverse myelitis. Tr. II at 120. He conducts also research, focusing on "mechanisms of inflammation of the spinal cord" in "spinal cord injury." Tr. II at 119; *see also* Tr. II at 184. In particular, Dr. Kerr is investigating the association between vaccines and transverse myelitis in "a prospective case[-]controlled study." Tr. II at 125-27; *see also* Tr. II at 145, 168. Like Dr. Mandler, Dr. Kerr is active in the Transverse Myelitis Association. *See* R. ex. B at 1; *see also* Tr. II at 147-48.

Describing Dr. Mandler as "a colleague and a friend," Tr. II at 161, Dr. Kerr offered that Dr. Mandler depicted "accurately" transverse myelitis as "a syndrome or a disorder" involving "focal" injury to the spinal cord. Tr. II at 122-23; *see also* Tr. II at 139, 168. Dr. Kerr said that in transverse myelitis, the immune system "becomes progressively deranged," Tr. II at 135, losing its ability "to distinguish self from non-self." Tr. II at 123; *see also* Tr. II at 168. Thus, Dr. Kerr said, the immune system is "tricked into" damaging "self tissues." Tr. II at 122-23; *see also* Tr. II at 127, 151. According to Dr. Kerr, the diagnosis of transverse myelitis depends upon "radiologic and spinal fluid findings of inflammation." Tr. II at 124; *see also* Tr. II at 168. Dr. Kerr stated the incidence of transverse myelitis is "[a]pproximately four to eight new cases per million people per year." Tr. II at 135.

Dr. Kerr identified at least two "largely environmental triggers" for transverse myelitis, adding that "some people are more genetically susceptible to" developing a condition like transverse myelitis. Tr. II at 123; *see also* Tr. II at 199. First, Dr. Kerr asserted that "infection" is "the most common cause, far and away," for transverse myelitis. Tr. II at 127. Second, Dr. Kerr acknowledged that "throughout history," transverse myelitis "has clearly been associated with vaccines," particularly "many of the older vaccines" like "smallpox," or "live vaccines" comprised of attenuated virus that is capable of replicating. Tr. II at 125-26; *see also* Tr. II at 153-54, 156-57, 159, 167, 169, 206. Dr. Kerr explained that some early vaccines contained "neural tissue" which caused "neurologic disease" when injected "into a human." Tr. II at 157; *see also* Tr. II at 153-54. Dr. Kerr indicated that the medical community's experience with the early vaccines "necessitated the development of more pure," modern vaccines. Tr. II at 157.

While Dr. Kerr maintained that he knows "[i]n fact" that the medical community does not embrace the proposition that modern "vaccines cause transverse myelitis," Tr. II at 125, he granted that he has "uncertainty" regarding the relationship between vaccines and neurologic injury. Tr. II at 145; *see also* Tr. II at 144. Dr. Kerr remarked that he can accept "[t]heoretically" a causal association between vaccines and neurologic injury. Tr. II at 146. But, Dr. Kerr declared that "causality" rests upon "a much higher standard than" temporal coincidence. Tr. II at 146. Thus, Dr. Kerr testified that to confirm causation, he requires either epidemiology based upon a solid "objective study," Tr. II at 126, or "biological evidence." Tr. II at 146; *see also* Tr. II at 128-29, 145, 167-68.

Yet, Dr. Kerr agreed that vaccines may have some role in the etiology of transverse myelitis. *See* Tr. II at 152; *see also* Tr. II at 144, 159. And, Dr. Kerr agreed that a person will develop more likely an aberrant immune response after a booster vaccination rather than after an initial vaccination. *See* Tr. II at 166. Indeed, Dr. Kerr proclaimed that Dr. Mandler's hypothesis "of a low level response" to initial vaccination "followed by a booster shot and then a more systemic, serious response is certainly theoretically reasonable, plausible, sound." Tr. II at 173.

Regardless, Dr. Kerr opined that Prevnar is not responsible for Lynze's transverse myelitis. *See* Tr. II at 122; *see also* Tr. II at 128, 139, 145, 173-74, 197. At the outset, Dr. Kerr announced that he has "[n]ever" encountered a report of transverse myelitis following a Prevnar vaccination. Tr. II at 135; *see also* Tr. II at 200. Next, Dr. Kerr differentiated Prevnar from early vaccines and from attenuated vaccines. *See* Tr. II at 206; *see also* Tr. II at 167. In particular, Dr. Kerr classified Prevnar as "a non-biologically active vaccine" that does not replicate. Tr. II at 167. Thus, Dr. Kerr urged that Prevnar does not have an increased "propensity for neurologic complication" like attenuated vaccines. *Id.* Then, Dr. Kerr challenged several aspects of Dr. Mandler's opinion. Dr. Kerr contended that a "molecular mimicry" theory is not valid in this case. *See* Tr. II at 133-34. According to Dr. Kerr, molecular mimicry "has never, ever been" implicated "in any disease caused by" the streptococcus bacteria used in Prevnar. Tr. II at 133-34. In addition, Dr. Kerr contended that a "superantigen" theory is not valid in this case. *See* Tr. II at 133, 170, 190-93. Dr. Kerr defined a "superantigen" as "a strange[,] chemically[-]produced protein" found "within" a bacteria rather than "on the surface of" a bacteria. Tr. II at 191; *see also* Tr. II at 132. According to Dr. Kerr, a superantigen "never has been isolated in any circumstances" in the streptococcus bacteria used in Prevnar. Tr. II at 192-93; *see also* Tr. II at 133, 170. Moreover, Dr. Kerr suggested that even if the streptococcus bacteria used in Prevnar included a superantigen, the manufacturing process for Prevnar would avoid the superantigen. *See* Tr. II at 192-93. Dr. Kerr explained that Prevnar is comprised only of "capsular proteins" from the surface of the streptococcus bacteria. Tr. II at 160; *see also* Tr. II at 132-34, 191-93. Finally, although ceding the presence of rash following Lynze's May 23, 2000 Prevnar vaccination, *see* Tr. II at 180-83, Dr. Kerr discounted Dr. Mandler's premise that Lynze's transverse myelitis represents an allergic booster reaction to Prevnar. *See* Tr. II at 179; *see also* Tr. II at 173-76. Dr. Kerr elaborated that if Lynze experienced an allergic booster reaction to Prevnar, he would expect Lynze to have exhibited "more pronounced" symptoms, like "rash," following her June 27, 2000 Prevnar vaccination. Tr. II at 179.

In any event, Dr. Kerr disputed that Lynze's transverse myelitis contributed to Lynze's speech deficits. *See* Tr. II at 139, 195. Dr. Kerr emphasized that transverse myelitis "is a focal inflammation of the spinal cord." Tr. II at 139; *see also* Tr. II at 168. Dr. Kerr insisted that "speech has nothing to do with spinal cord dysfunction." Tr. II at 139. And, Dr. Kerr indicated that the record does not reflect evidence of a disseminated process, or "brain involvement." Tr. II at 195-96; *see also* Tr. II at 139.

THE INSTITUTE OF MEDICINE

Congress directed the Secretary of the Department of Health and Human Services to contract with the Institute of Medicine (IOM)–the august division of the National Academy of Sciences (NAS) chartered in 1970–or with "other appropriate nonprofit private groups or associations" to canvass scientific and medical evidence regarding adverse consequences of routine childhood vaccines. National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, §§ 312-13, 100 Stat. 3779-82 (1986). The IOM publishes conclusions from its reviews. *See e.g.*, Christopher P. Howson, *et al*., INSTITUTE OF MEDICINE, ADVERSE EFFECTS OF PERTUSSIS AND RUBELLA VACCINES (National Academy Press 1991); Kathleen R. Stratton, *et al.*, INSTITUTE OF MEDICINE, DPT VACCINE AND CHRONIC NERVOUS SYSTEM DYSFUNCTION: A NEW ANALYSIS (National Academy Press 1994); Kathleen R. Stratton, *et al*., INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY (National Academy Press 1994). Special masters deem commonly the IOM's conclusions to be authoritative. *See, e.g.*, *Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290, *10 (Fed. Cl. Spec. Mstr. Jan. 23, 1998); *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984, *8 n.15 (Fed. Cl. Spec. Mstr. July 31, 2001) citing *Asche-Robinson v. Secretary of HHS*, No. 94-1096V, 1998 WL 994191, *7-8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998).

The IOM has considered the general relationship between vaccines and demyelinating diseases of the central nervous system, including transverse myelitis. *See* Kathleen R. Stratton, *et al*., INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY at 34-48, 83-86 (National Academy Press 1994). The IOM describes transverse myelitis as "the acute onset of signs of spinal cord disease, usually involving the descending motor tracts and the ascending sensory fibers, suggesting a lesion at one level of the spinal cord." *Id.* at 37. According to the IOM, when transverse myelitis does not occur in conjunction with a "diffuse demyelinating" condition, like acute disseminated encephalomyelitis (ADEM), the "mechanisms and pathologies" of transverse myelitis "are usually unknown." *Id.* at 36-37. Nevertheless, the IOM indicates that the medical community suspects that transverse myelitis is a "unifocal" event "of demyelination." *Id.* at 37.

The IOM acknowledges that demyelinating diseases of the central nervous system "can occur after the administration of either live attenuated or killed vaccines (in the case of vaccinia virus and the swine influenza vaccines, respectively.)" Kathleen R. Stratton, *et al*., INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY at 47 (National Academy Press 1994). Therefore, the IOM recognizes as "biologically plausible" the proposition that a vaccine "might induce in the susceptible host" a demyelinating disease of the central nervous system. *Id.* at 48. The IOM postulates that the process may occur through "an autoimmune response by deregulation of the immune system, by nonspecific activation of the T cells directed against myelin proteins, or by autoimmunity triggered by sequence similarities of proteins in the vaccine to host proteins such as those of myelin." *Id.* The IOM estimates that demyelinating diseases of the central nervous system "occur after an interval of 5 days to 6 weeks following . . . injection of" an "antigen." *Id.* at 47.

DISCUSSION

This case presents an issue that is all too common in recent Program cases: the intellectual rigor demanded in the evaluation of a claim under the actual causation standard. The actual causation standard suggests at least two methods of analyzing evidence of causation. One method is rote, nearly formulaic really. The special master ensures simply that a petitioner's expert espouses a hypothesis, no matter how "innovative," regarding a vaccine and an injury that is grounded in some medical or scientific principle, *see, e.g.*, *Daubert*, 509 U.S. at 593-94; reviews the record as a whole, considering factors such as a petitioner's condition before vaccination and a petitioner's clinical course after vaccination; and confirms that the period between vaccination and the injury is reasonable enough to ascribe the injury to vaccination. *See, e.g.*, *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1358 (Fed. Cir. 2006)(noting that an injury that occurs "within a medically[-]acceptable time frame" after vaccination "bolsters a link between the injury alleged and the vaccination"). Another method is more critical. The special master assesses comprehensively the scientific or medical validity of an expert's hypothesis and canvasses the record for concrete evidence verifying the applicability of the expert's hypothesis to the case.

Respondent advocates naturally a stricter approach to analyzing evidence of causation. In briefing, respondent dissects aspects of Dr. Mandler's testimony, concluding that Dr. Mandler's opinion "is unreliable and lacks *any* convincing support whatsoever, scientific or otherwise." Respondent's Memorandum Regarding *Althen v. HHS* and *Rodriguez v. HHS* (R. memo) at 9 (emphasis in original). Respondent charges that Dr. Mandler offered "no medical literature discussing Prevnar vaccine and transverse myelitis;" or "case reports of transverse myelitis following Prevnar;" or "case reports of any autoimmune disease following Prevnar;" or "animal studies." *Id.* Likewise, respondent charges that Dr. Mandler cited "no contemporaneous medical records drawing a causal connection between Prevnar and Lynze's" transverse myelitis. *Id.*

Yet, respondent ignores largely Dr. Mandler's basic premise: Vaccines are legitimate environmental triggers in the development of transverse myelitis because vaccines are designed solely to stimulate a recipient's immune system and because the medical community believes that transverse myelitis is the result of an aberrant response to a stimulus to the immune system. *See, e.g.*, Tr. II at 44, 58, 112-15. Indeed, Dr. Mandler did not profess to know an exact mechanism for transverse myelitis. *See, e.g.,* Tr. II at 36, 44-50, 56, 61-62, 95. Rather, Dr. Mandler discussed merely several widely-held medical views regarding potential mechanisms for transverse myelitis. *See, e.g.*, Tr. II at 36, 44-50, 56, 95-96. And, the IOM lends surely significant credence to Dr. Mandler's overall testimony.

One cannot fault respondent's desire to impose stringent scientific or medical scrutiny upon actual causation claims in the Program. After all, the Federal Circuit has signaled that special masters should understand and apply the Act as a medical professional would understand and apply the Act. *See, e.g.*, *Abbott v. Secretary of HHS*, 19 F.3d 39 (Fed. Cir. 1994)(affirming in part, reversing in part and remanding *Abbott v. Secretary of HHS*, 27 Fed. Cl. 792, 793-94 (1993)); *see also Shyface*, 165 F.3d at 1349. Nevertheless, the Federal Circuit has counseled certainly that special

masters are not to delve into "research" reserved "for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies" by "ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others." *Knudsen*, 35 F.3d at 549. Moreover, respondent's position is not consistent with the current direction of Federal Circuit precedents. According to the Federal Circuit, "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft* of complete and direct proof of how vaccines affect the human body" by permitting specifically a petitioner to introduce "circumstantial evidence" in the presentation of a claim. *Althen*, 418 F.3d at 1280, citing *Knudsen*, 35 F.3d at 549 (emphasis added); *see also Capizzano*, 440 F.3d at 1325; *but see Munn v. Secretary of HHS*, 970 F.2d 863, 865 (Fed. Cir. 1992)(recognizing that, in contrast to the Act's provision for a presumption of causation in certain circumstances, an actual causation claim involves "a more difficult evidentiary showing," and that "[g]iven the vagaries of human illnesses," the preponderance of evidence burden "is not always an easy burden to carry"); *Hodges v. Secretary of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993)(commenting that "[g]iven the statutory burden of persuasion placed upon the petitioner, 42 U.S.C. § 300aa-13(a)(1), and the general state of medical knowledge about the causes of" particular conditions, "it is not surprising that petitioners have a difficult time proving" actual causation claims). Thus, in Program proceedings, a special master cannot compel absolute proof supporting a relationship between a particular vaccine and a particular condition. *See, e.g.*, *Rodriguez v. Secretary of HHS*, No. 03-0087V, 67 Fed. Cl. 409, 411 (2005). And, according to the Federal Circuit, special masters are to resolve "close calls regarding causation" for "injured claimants." *Althen*, 418 F.3d at 1280, citing *Knudsen*, 35 F.3d at 549; *see also Capizzano*, 440 F.3d at 1325-26.

Regardless, this case is not necessarily "close." Dr. Mandler and Dr. Kerr possess stellar professional credentials. They are colleagues, peers, and, apparently, friends. *See, e.g.*, Tr. at II at 39, 161. They concur on certain, fundamental aspects of the case. They agree completely that transverse myelitis is a rare, autoimmune syndrome characterized by inflammation and by damage to the spinal cord. *See, e.g.*, Tr. II at 30, 36, 44-46, 50, 54, 57, 66, 82-83, 86, 89, 102, 122-24, 127, 135, 139, 151, 168. In addition, they agree that Lynze suffered at a minimum transverse myelitis in July 2000. *See, e.g.*, Tr. II at 42, 122. Based upon Lynze's speech delay diagnosed apparently in August 2001, *see, e.g.*, Pet. ex. at 181, 283, Dr. Mandler advanced that Lynze may have sustained in July 2000 a more diffuse condition than transverse myelitis, involving central nervous system structures beyond her spinal cord. *See, e.g.*, Tr. II at 81-82, 84, 86, 89, 91-92. Thus, Dr. Mandler would label Lynze's illness in July 2000 as "transverse myelitis plus." Tr. II at 82; *see also* Tr. II at 91. In contrast, Dr. Kerr asserted that Lynze's medical records from July 2000 do not reflect "brain involvement" as a component of Lynze's condition in July 2000. Tr. II at 195-96; *see also* Tr. II at 139. Thus, Dr. Kerr concluded that Lynze's injury in July 2000 was limited to "spinal cord dysfunction," which "has nothing to do with" development of "speech." Tr. II at 139; *see also* Tr. II at 195. As a consequence, Dr. Kerr would not relate Lynze's later speech deficits to Lynze's transverse myelitis in 2000. *See, e.g.*, Tr. II at 139, 195. Further, they agree partially that the medical community has implicated vaccines as a cause of transverse myelitis. *See, e.g.*, Tr. II at 44, 50-51, 57, 112-14, 125-26, 153-54, 156-57, 159, 169. Although Dr. Kerr acknowledged an historic association between particular types of vaccines and transverse myelitis, *see, e.g.*, Tr. II at 125-26,

153-54, 167, 169, 206, Dr. Kerr maintained that today's medical community does not accept that "vaccines cause transverse myelitis." Tr. II at 125. According to Dr. Kerr, there does not exist yet either adequate "epidemiological evidence" or adequate "biological evidence" supporting "causality" between vaccines and transverse myelitis. Tr. II at 146; *see also* Tr. II at 126, 128-29, 145.

However, the Act does not require the Fants to establish their medical theory at the level of certainty that Dr. Kerr seeks. *See, e.g*, *Knudsen*, 35 F.3d at 548-49. Indeed, Dr. Kerr conceded that "there may be a relationship" between vaccines and transverse myelitis. Tr. II at 143-46. Therefore, the special master finds sufficient evidence in the record to conclude that an antigen, like Prevnar vaccine, is capable of provoking an autoimmune response resulting in a demyelinating condition, like transverse myelitis.

Lynze was well when she received a DTaP vaccination, IPV and a Prevnar vaccination on May 23, 2000. *See* Pet. ex. at 12. Lynze received a second Prevnar vaccination on June 27, 2000. *See* Pet. ex. at 2. On July 5, 2000–just six weeks after her May 23, 2000 vaccinations and eight days after her June 27, 2000 vaccination–Lynze sustained transverse myelitis. *See generally* Pet. ex. at 16-167. Lynze's transverse myelitis occurred definitely within the relevant period that the IOM cites for demyelinating diseases of the central nervous system "following . . . injection of" an "antigen." Kathleen R. Stratton, *et al*., INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY at 47 (National Academy Press 1994).

Dr. Mandler opined that Lynze's June 27, 2000 Prevnar vaccination is "the most likely cause of" Lynze's transverse myelitis. Tr. II at 42-43; *see also* Tr. II at 58. In Dr. Mandler's view, Lynze's May 23, 2000 Prevnar vaccination sensitized Lynze's immune system. *See* Tr. II at 46-48, 63-64, 96, 114-15. Then, Lynze's June 27, 2000 Prevnar vaccination ignited "a mega" immune "response," Tr. II at 63; *see also* Tr. II at 61, or an abnormal "booster" effect, Tr. II at 46-48; *see also* Tr. II at 63-64, 96, 144-15, resulting in Lynze's transverse myelitis. At some level, Dr. Kerr considered Dr. Mandler's opinion to be "certainly theoretically reasonable, plausible, sound." Tr. II at 173.

The special master determines that the Fants have demonstrated by the preponderance of the evidence that Lynze's June 27, 2000 Prevnar vaccination is the legal cause of Lynze's transverse myelitis. Likewise, the special master determines that there is not a preponderance of the evidence that Lynze's transverse myelitis is due to factors unrelated to the administration of Lynze's June 27, 2000 Prevnar vaccination. By definition, transverse myelitis is a spinal cord condition. *See, e.g.*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1209 (30th ed. 2003); Tr. II at 92, 139. As a consequence, the special master determines that the Fants have not demonstrated by the preponderance of the evidence that Lynze's June 27, 2000 Prevnar vaccination or Lynze's transverse myelitis contributed in any way to Lynze's speech deficits. Therefore, the Fants are entitled to Program compensation for Lynze's transverse myelitis and the acute complications or sequelae of Lynze's transverse myelitis, but not for Lynze's speech delay.

DAMAGES

On February 15, 2007, respondent filed a proffer reflecting respondent's recommendation on damages in this case. *See* Respondent's Proffer on Award of Damages (Proffer), filed February 15, 2007. The Fants agree with all aspects of the Proffer. *See generally* Proffer. Based upon the record as a whole, the special master finds that the Proffer is reasonable and appropriate.[8]

CONCLUSION

1. As provided in the Proffer, respondent shall pay as soon as practicable after entry of judgment $178,765.37 in a lump sum to PeoplesBank, a Codorus Valley Company, as trustee of a Grantor Reversionary Trust established for the benefit of Lynze Fant. *See* Proffer at 2-3, ¶ II(A); Proffer at 5, ¶ III(A). The amount represents the total of the current value of compensation for licensed practical nursing care for year 2008 through year 2013; the current value of compensation for cleaning services for year 2040 through year 2049; and compensation for Lynze's life care expenses in the year following judgment. *See* Proffer at 5, ¶ III(A); *see also* § 300aa-15(a)(1)(A).

2. Respondent shall purchase, and take ownership of, as soon as practicable after entry of judgment an annuity contract that will provide during Lynze's lifetime the amount reflected in the Proffer, Appendix A, for each year after the one-year anniversary of entry of judgment. *See* Proffer at 1, ¶ I(A); Proffer at 3-4, ¶ II(D); Proffer at 5, ¶ III(D); *see also* § 300aa-15(a)(1)(A). The annuity payments shall be payable to PeoplesBank, a Codorus Valley Company, as trustee of a Grantor Reversionary Trust established for the benefit of Lynze Fant, only so long as Lynze is alive at the time a particular payment is due. *See* Proffer at 3-4, ¶ II(D). *As provided in the Proffer, the annuity contract shall provide for a 4% compounded annual growth rate for all non-medical life care items listed in Proffer, Appendix A. See* Proffer at 4, ¶ II(D)(1). *As provided in the Proffer, the annuity contract shall provide for a 5% compounded annual growth rate for all medical life care items listed in Proffer, Appendix A. See* Proffer at 4, ¶ II(D)(1). *As provided in the Proffer, the growth rate shall be applied and compounded beginning on the date of judgment. See*

[8] By reference, the special master incorporates respondent's Proffer into this decision on entitlement and damages.

Proffer at 4, ¶ II(D)(1). The insurer from whom respondent shall purchase the annuity contract must meet two criteria:

> a. The company must have a minimum of $250,000,000.00 of capital and surplus, exclusive of any mandatory security valuation reserve; and
>
> b. The company must have one of the following ratings from two of the following rating organizations:
>
> (i) A.M. Best Company: A++, A+, A+g, A+p, A+r, or A+s;
>
> (ii) Moody's Investor Service Claims Paying Rating: Aa3, Aa2, Aa1 or Aaa;
>
> (iii) Standard and Poor's Corporation Insurer Claims-Paying Ability Rating: AA-, AA, AA+ or AAA;
>
> (iv) Fitch Credit Rating Company Insurance Company Claims Paying Ability Rating: AA-, AA, AA+ or AAA.

See Proffer at 3, n.2.

3. As provided in the Proffer, respondent shall pay as soon as practicable after entry of judgment $133,160.68 in a lump sum to Jerril Fant and Dawn Fant, as court-appointed guardians/conservators of the estate of their daughter, Lynze Fant, for the benefit of Lynze Fant. *See* Proffer at 2, ¶ I(C); Proffer at 3, ¶ II(B); Proffer at 5, ¶ III(B). The amount represents compensation for Lynze's actual and

projected pain and suffering and emotional distress. *See* Proffer at 2, ¶ I(C); Proffer at 3, ¶ II(B); *see also* § 300aa-15(a)(4).

4. As provided in the Proffer, respondent shall pay as soon as practicable after entry of judgment $32,139.85 in a lump sum to Jerril Fant and Dawn Fant. *See* Proffer at 2, ¶ I(D); Proffer at 3, ¶ II(C); Proffer at 5, ¶ III(C). The amount represents compensation for unreimbursable expenses before the date of judgment. *See* Proffer at 3, ¶ II(C); *see also* § 300aa-15(a)(1)(B). The parties represent that there exists no Medicaid lien. *See* Proffer at 2, ¶ I(E).

5. The special master determines that the Fants are not entitled to an award of compensation for Lynze's lost future earnings. *See* Proffer at 2, ¶ I(B); *see also* § 300aa-15(a)(3)(B).

In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment in the Fants' favor in complete conformity with this decision. Under Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing the right to seek review. Then, under Vaccine Rule 12(a), the Fants may expedite payment by filing an election to accept the judgment.

The clerk of court shall send the Fants' copy of this decision to the Fants by overnight express delivery.

_____
John F. Edwards
Special Master